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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,730

10/11/2005

Federico Nalesso

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30904

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03/25/2009

MODIANO & ASSOCIATE  
VIA MERA VIGLI I6  
MILAN, 20123  
ITALY

EXAMINER

MELLON, DAVID C

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,730	<b>Applicant(s)</b> NALESSO, FEDERICO	
	<b>Examiner</b> DAVID C. MELLON	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20051011</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 14-21 in the reply filed on 3/10/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 14-21 are pending, claims 1-13 and 22-26 were cancelled by the applicant.

### ***Specification***

2. The disclosure is objected to because of the following informalities:
- On P1/L11, "sepses" should be corrected with "sepsis" to maintain continuity throughout the application.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 16, the recitation of the phrase "said plasma purification circuit is filtered by said stage for filtering plasma" renders the claim indefinite. It is unknown how

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one would filter a fluid circuit. One would filter the fluid in a fluid circuit, but not the apparatus. The claim is generally unclear and makes no apparent grammatical sense.

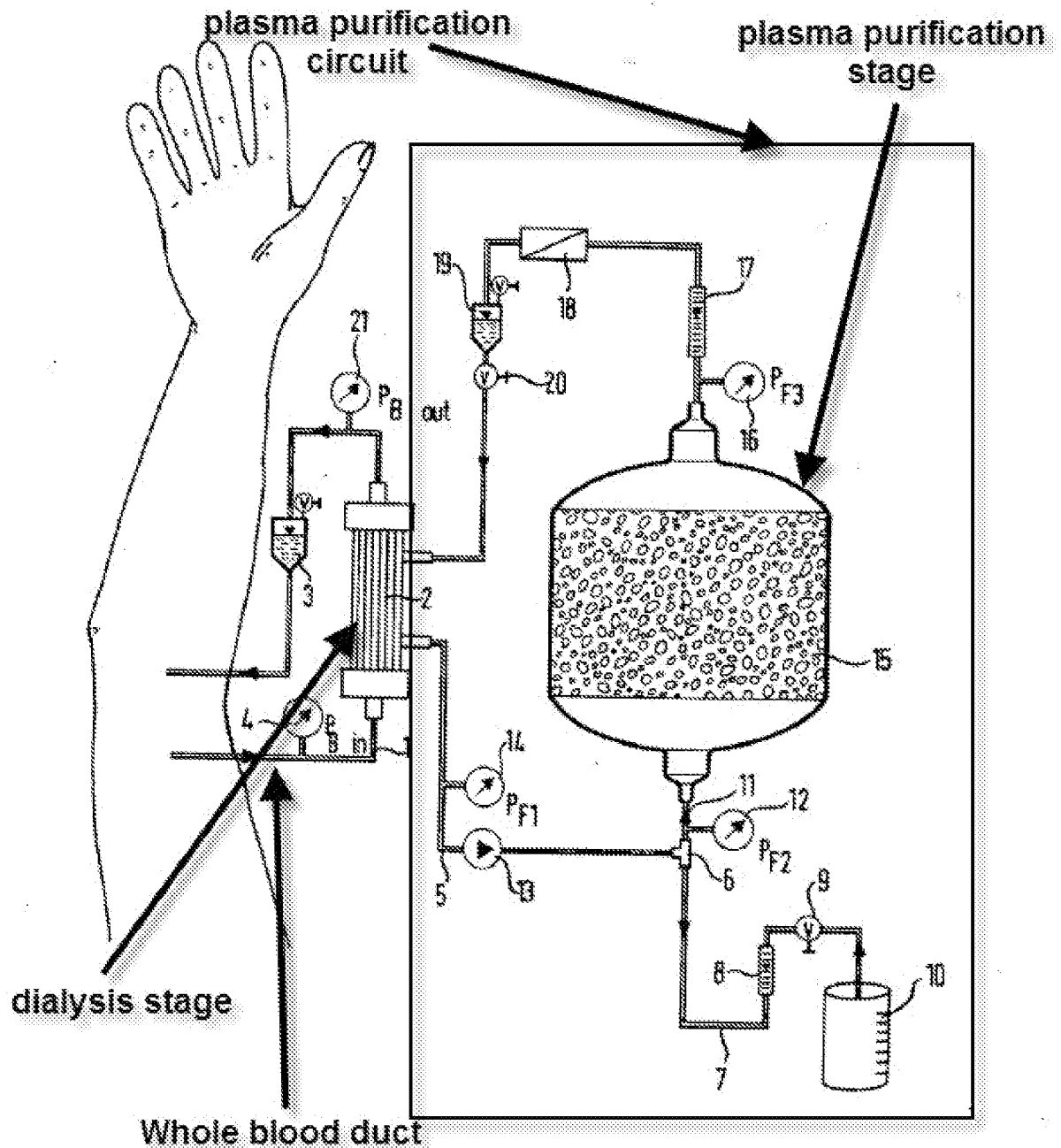
***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**6. Claims 14, 16-18, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shettigar (GB 2124511).**



Regarding claim 14, Shettigar discloses an apparatus for the purification of blood (Abstract) in figure 1 and annotated figure above, comprising:

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- A duct for the flow of whole blood (1 - conduction system)
- A stage for filtering plasma from the whole blood arranged along said duct (filter 15 for instance)
- A plasma purification circuit and connected with the plasma filtering stage (see annotated figure above)
- A stage for whole blood dialysis by means of plasma purified in said circuit, said stage for whole blood dialysis comprising a selectively permeable interface for separating at least part of the whole blood stream of said duct from a countercurrent stream of plasma purified in said circuit (2, see also P4/L1-40).

Regarding claim 16, Shettigar further discloses the plasma purification stage is connected to the dialyzing stage of the blood and connected downstream of the dialyzer stage (see figure and functional relationships between 15, 2, and the attaching ductwork).

Regarding claims 17 and 18, Shettigar further discloses a device for removing water-soluble and dialyzable toxic molecules that uses membrane-based adsorptive processes (15 - P4/L83-105 - carbon cartridges are membrane filters).

Regarding claims 20 and 21, Shettigar further discloses the unit (15) has a carbon adsorptive cartridge (P4/L83-105 - cartridge would be equivalent to column).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shettigar (GB 2124511) and in view of Baudet et al. (USP 4,038,190).**

Regarding claim 15, Shettigar discloses all of the claim limitations as set forth above. Shettigar does not explicitly disclose the parallel permeable capillaries separated by a wall with a gap in the wall.

Baudet et al. discloses a hollow fiber fluid fractioning apparatus (abstract) in figure 23 comprising:

- A core (1 - which acts as the wall between the chambers)
- Tubes (12 and 13) for plasma flow
- Tubes (17 and 18) for blood flow
- Orifice (14) through which fluid passes in the core from hollow fiber set one to the second set (2 and 2' are hollow fiber or capillaries).

Shettigar and Baudet et al. are combinable because they are concerned with the same field of endeavor, namely that of membrane units.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dialysis separation system of Shettigar to replace the hollow fiber unit (2) of Shettigar with the membrane system as disclosed in figure 2 of Baudet et al. for the purpose of improved fluid purification in a counter current operation system.

**10. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shettigar (GB 2124511) and in view of Mishiro et al. (USP 4,340,481).**

Regarding claims 17-19, Shettigar discloses all of the claim limitations as set forth above. Shettigar does not explicitly set forth a dialyzer system assembly which utilizes a dialysate tank, used dialysate tank, and an infusate tank.

Mishiro et al. discloses a membrane filtration hollow fiber system (Abstract) in figure 10 comprising:

A dialysate tank, a dialyzer, an infusate tank, and a used dialysate tank.

Shettigar and Mishiro et al. are combinable because they are concerned with the same field of endeavor, namely that of membrane units.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the purification loop of Shettigar to further include a membrane dialyzer with assorted tanks as taught by Mishiro et al. for the purpose of improved dialysis performance and reduced risk of infection.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is



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(571)270-7074. The examiner can normally be reached on Monday through Thursday 7:00am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/  
Primary Examiner, Art Unit 1797

/D. C. M./  
Examiner, Art Unit 1797